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09/656,435	09/06/2000	Akiko Itai	195832US	9728

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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/656,435

Applicant(s)

ITAI ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

117

## DETAILED ACTION

### *Status of Claims*

1. Pursuant to petition filed 02/11/2005, the abandonment of 02/08/2005 is vacated. The reply mailed 10/14/2003, which has not been entered into eDAN system previously, is now entered. All previously pending claims are canceled and new claims 14-16 are added.

### ***Claim Rejections - 35 USC § 112, second paragraph.***

2. Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

A. Claim 14: The preamble recites that the objective of the method of the claim is to “predict” stable docking configuration of heteroatoms in a ligand. If “predicting” follows from the previous step of “selecting configuration”, it is not clear how a “stable docking configuration of heteroatoms” can be predicted, if the only result of preceding method steps is placing heteroatom in an arbitrary position, placing dummy atom into the same position, and then positioning heteroatom back in position corresponding to the dummy atom. Note that step C) of the method is seemingly unrelated to other method steps, and thus it is not clear if it has any impact on the final result of the method.

B. Claim 15: Similarly to the previous rejection of claim 14, for claim 15 it is not clear conformation of ligand that binds to biopolymer can be “predicted” from moving around heteroatoms of ligand, without any nexus to ligand-biopolymer interaction.

Art Unit: 1631

B. Claim 14, preamble: The meaning of term “for corresponding” in the phrase “... docking configuration of ...heteroatoms in ligand for corresponding groups in a ligand binding region” is not clear. Does “for corresponding” mean docking configuration of heteroatoms in ligand in the complex, or docked configuration, with ligand. If yes, then it is not clear how the method achieves such result because the method steps do nothing but changing coordinates of heteroatoms in the ligand itself, which is unrelated to docked configuration, with ligand binding region.

C. Claims 14, 15: The term “arbitrary conformation” is a relative term and it is not clear what constitutes “arbitrary conformation”.

D. Claim 14, preamble: The term “stable” in regard to “docking configuration of heteroatoms” is not clear. The method steps are limited to positioning heteroatoms and dummy atoms in arbitrary positions in space, there are no steps to determine any “stability”; therefore, the meaning of this term is not clear.

Applicant argues that the term “stable” can be understood as energetically stable if read in view of specification. However, the method steps are unrelated to any manipulations with, or identification of energy states, therefore the term “stable” remains unclear.

E. Claims 14,15, step A): it is not clear which “coordinates” are meant at the end of the claims as two different coordinates, of ligand and ligand binding region, has been entered.

F. Claims 14,15, step D. The steps involved in the “selecting” are not clear. From the claim language it seems that the heteroatoms are placed in their original position

Art Unit: 1631

addressed in the first method step, step A, because, according to step B, dummy atoms are placed in position of heteroatoms, and, according to step D, in reverse, the heteroatoms are placed back in position of dummy atoms.

Applicant argues that specification teaches "selecting" based on energy of the docking configuration. However, the method steps are unrelated to determination of biopolymer-ligand configuration, much less of its energy – all the method steps are directed to is placing heteroatom of ligand itself in an arbitrary position, placing dummy atom into the same position, and then positioning heteroatom back in position corresponding to the dummy atom.

As addressed in previous Office actions, the term "selecting" remains vague and indefinite. Specification discussed selecting "possible" docking structures, but criteria for selection of such structures are not clear. There is no nexus to biopolymer-ligand interaction.

***Claim Rejections - 35 USC § 112, first paragraph.***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 14-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is maintained for the same reasons as previously applied to claims 12,13. The new claims

14-16, same as the previously submitted claims 12,13 (now canceled), are drawn to methods wherein the heteroatoms, after performing method steps, are positioned in their original position - note that it seems that the heteroatoms are placed in their original position addressed in the first method step, step A, because, according to step B, dummy atoms are placed in position of heteroatoms, and, according to step D, in reverse, the heteroatoms are placed back in position of dummy atoms. The specification, in contrary, addresses methods comprising evaluating hydrogen bond schemes in ligand-biopolymer interactions.

Applicant argues that submission of new claims 14-16 instead of claims 12,13, obviates the rejection. However, Examiner maintains that the new claims have the same problems as claims 12,13 before them.

### ***Double Patenting***

4. Claims 14-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of US patent 5,642,292. The claims of the parent application recite methods which comprise method steps as instantly claimed. See claim 2, for example:

2. A method which comprises:

preparing exhaustive combinational sets of the correspondences between dummy atoms and the hydrogen-bonding atoms in a ligand, said dummy atoms being preset on the positions of heteroatoms that can be partners to the hydrogen-bonding of the hydrogen-bonding functional groups in a biopolymer,

comparing, for each correspondence, the distances between the dummy atoms with the distances between the corresponding hydrogen-bonding heteroatoms in the ligand with the conformation of the ligand being changed regularly,

thereby selecting combinations of favorable correspondences between the dummy atoms and the heteroatoms with conformations of the ligand,

Art Unit: 1631

generating the possible structures of the complex by fitting said ligand into the coordinate system of said biopolymer on the basis of said favorable correspondences, and

estimating the possible schemes of binding between the biopolymer and a hydrogen-bonding part of the ligand simultaneously with the possible conformations of said hydrogen-bonding part.

Note, that double-patenting rejection over claims 1-8 of US Patent 6,308,145 which has been applied to claim 13 (now canceled), is withdrawn because the '145 claims are directed to docking structures between ligand and biopolymer, while the instant claims, while mentioning biopolymer, are directed to heteroatom locations of ligand alone. If the instant claims are amended to be directed to docking structures between ligand and biopolymer, the double patenting rejection over US Patent 6,308,145 will be reconsidered.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin, Ph.D.  
Primary Examiner  
Art Unit 1631



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